TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 01-14-88 OUT 02-04-88

Dennis G. Guse WEG 2-8-88

Reviewed By Dennis G. Guse Date 02-04-88

EPA Reg. No. or File Symbol 56796-R

EPA Petition or EUP No. None

Date Division Received 01-12-88

Type Product Medical Device Manufacturing Sterilant

Data Accession No(s). MRID 404678-01

Product Manager 32 (Kempter)

Product Name Scopas Sterilization System Cartridge: Sodium Chlorite/ Chlorine for Generation of Chlorine Dioxide

Company Name Scopas Technology Company

Submission Purpose Resubmission for new product registration with additional data

Type Formulation Sodium chlorite (dry) + soda lime (granules) in cartridge to be combined with external chlorine

Active Ingredient(s):	%
Sodium chlorite	79

200.0 Introduction

200.1 Background

Refer to the previous reviews for this product by TSS (Efficacy) dated 09-14-87, 08-07-87, and 03-19-87.

200.2 Current Submission

The current submission consists of additional AOAC Sporicidal Test data in a prototype model of the proposed chlorine dioxide gas sterilization system.

201.0 Data Summary

201.1 Brief Description of Tests (MRID 404678-01)

"Scopas AOAC Sterility Studies to Demonstrate Efficacy of Chlorine Dioxide Gas in a Sterilization Chamber - Final Report." Report by Dr. Joseph E. Knapp, University of Pittsburgh, Pittsburgh, PA, and Daniel Drozdowski, United States Testing Company, Inc., Hoboken, NJ, dated January, 1988.

201.2 Test Summaries

a. Objective: Determination of effectiveness of the Scopas chlorine dioxide gas sterilizing system with simulated product loads using the AOAC Sporicidal Test procedure.

b. Method: AOAC Sporicidal Test.

c. Test Product: Chlorine dioxide gas generated by passage of moisterized nitrogen-diluted chlorine gas through a column of sodium chlorite and then passed into the sterilization chamber. Three different columns of sodium chlorite were used, one for each set of exposures designated as Trials #1, #2, and #3.

d. Exposure Chamber: A 2-cubic foot stainless steel chamber with automated process controller and monitoring instrumentation. See the attached operation decription and schematic diagram.

e. Concentration: 40 mg/liter of chlorine dioxide gas.

f. Temperature: 22.0 to 29.9°C.

g. Time: 18 hours.

h. Pressure: Atmospheric.

i. Humidification: Prehumidification (prior to gas exposure) for 3 hours at 95% or higher relative humidity under 25 in. Hg vacuum. Humidification was maintained during exposure to the gas at 92.0 to 96.6% relative humidity at atmospheric pressure. (Note: In Trial #1, high relative humidity was maintained only intermittantly after 12 hours of exposure.)

j. Test Organisms: Spores of Bacillus subtilis ATCC 19659 (resistance to 2.5 N HCl was at least 2 minutes on cylinders and suture loops) and Clostridium sporogenes ATCC 3584 (resistance to 2.5 N HCl was at least 2 minutes on cylinders and suture loops).

k. Carriers: Porcelain penicylinders and cotton (instead of silk) suture loops (Refer to 201.2(c)(1)(Q), (R), & (S) in the previous review by TSS (Efficacy) dated 03-19-87.).

Carriers were prepared at U. S. Testing Co. in Hoboken, NJ, and shipped to University of Pittsburgh for exposure. For shipment, contaminated carriers were transferred to sterile petri dishes and packaged in polyethylene bags containing a dessicant pack. The bags were sparged with nitrogen and heat-sealed.

l. Test packaging: Carriers received at Pittsburgh from U. S. Testing Co. were individually transferred into 16x150 mm glass culture tubes capped with plastic slip caps (Bellco Glass Co.). The tubes were then heat-sealed in groups of 5 into 6x10 in. Tyvek-Mylar bags (Tower Plasti-Peel Gas Sterilization Pouches, American Hospital Supply Co.), for a total of 48 bags per trial.

Prior to Trial #3, it was noted that the plastic slip caps on hand sealed so tightly that moisture could not enter the glass tubes. Therefore, 3 small pinholes were drilled into each cap to allow humidification of the carriers.

After exposure, the packages were removed from the chamber and sealed into pre-sterilized polypropylene autoclavable biohazard bags (19x23 in.) (Fisher Chemical Co.) for shipment to U. S. Testing Co. The sealed bags were then packaged in cardboard boxes and shipped.

m. Subculture Medium/Neutralizer: Fluid thioglycollate medium.

n. Incubation: 21 days at 37°C, then heat-shocked for 20 min. at 80°C and re-incubated for 3 days at 37°C.

o. Results:

Trial #	Test Date	Exp. Time (hours)	Gas Conc. (mg/l) Init.	Gas Conc. (mg/l) Final	Temp. (°C) Init.	Temp. (°C) Final	Positive/Total Carriers B. subtilis SL	B. subtilis PC	C. sporogenes SL	C. sporogenes PC
1	6/18/87	18	34	44	25	28	0/60	0/60	0/60	0/60
2	7/16/87	18	39	44	26	30	0/60	0/60	0/60	0/60
3*	12/03/87	18	38	44	22	29	0/60	0/60	0/60	0/60

*Two initial runs of Trial #3 were disqualified due to procedural problems. Causal factors were identified as (1) Change in loading configuration which deviated from the protocol and from that of Trials #1 and #2, and (2) Problem with over-tight fit of the plastic slip caps on the glass tubes which prevented the introduction of moisture. Subsequently, difficulties were also encountered with the quality of the porcelain cylinders (new cylinders were obtained) and with the HCl resistance of the B. subtilis spores (incubation time was increased to 5 days).

p. Conclusions: Results show no failures out of 720 carriers in 3 trials exposed to chlorine dioxide gas generated from 3 different columns of dry sodium chlorite reacted with chlorine gas at a concentration of 40 mg/liter for 18 hours at ambient temperature and atmospheric pressure.

q. Comments: No adverse comments.

201.3 General Summary

The submitted data support effectiveness of chlorine dioxide gas as a sterilant in the proposed system, as follows:

a. Generation of the gas from dry columns of sodium chlorite reacted with chlorine as described for the cartridge system.

b. Pre-humidification and gas exposure carried out in a prototype model gas sterilization chamber equipped with automated process controller and monitoring instrumentation as described for the gas sterilization system.

c. Demonstration of sterilant efficacy under the following conditions:

1. Humidification under vacuum (25 inches Hg) at 95% relative humidity for 3 hours at ambient temperature prior to introduction of the gas.

2. Chlorine dioxide concentration of 40 ($\pm$5) mg/liter.

3. Relative humidity greater than 90%.

4. Ambient temperature (26 $\pm$4^{o}C).

5. Normal (atmospheric) pressure.

6. Exposure time of 18 hours.

d. The above data, developed by the AOAC Sporicidal Test at the University of Pittsburgh and U. S. Testing Co. with an automated prototype model of the dry gas generation system proposed for registration, together with previously submitted data by the AOAC Sporicidal Test at U. S. Testing Co. and Hazelton Biotechnologies Corp. with a manual lab model wet gas generation system, are considered sufficient to meet both the basic and confirmatory data requirements to support effectiveness of this product as a sterilizer.